Barr Laboratories, Inc.

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December 23, 2002

Food and Drug Administration
Dockets Management Branch (HFA-305)
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Docket No. 02N-0417: Proposed Rule—Patent Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications

Dear Sir or Madam:

Barr Laboratories, Inc. (Barr) hereby submits its comments on the Food and Drug Administration's (FDA's) proposed rule regarding the requirements for "listing" patents in FDA's "Orange Book" and the automatic 30-month stay of generic drug approval under the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman amendments").

Barr commends President Bush and FDA for recognizing the need for immediate reform to "ensure that lower cost, effective generic drugs become available to Americans without any improper delays." *Presidential Remarks* (Oct. 21, 2002). Over the past several years, certain brand-drug companies have discovered new ways to abuse the patent listing and 30-month stay provisions of the Hatch-Waxman amendments to delay the availability of affordable generic pharmaceuticals. The Federal Trade Commission's (FTC's) July 2002 report entitled "Generic Drug Entry Prior to Patent Expiration" confirmed that the patent listing and 30-month stay abuses are hindering competition and artificially maintaining monopoly prescription drug prices, to the detriment of consumers. FDA's proposed rule attempts to address the problems that FTC identified by defining the types of patents that may, and may not, be "listed" in the "Orange Book" and by limiting new drug application (NDA) holders to a single 30-month stay of the approval of competing generic drug applications.

The proposed regulatory reforms squarely address the issues that are delaying generic drug approval and costing consumers millions of dollars in lost savings. Barr therefore wholeheartedly supports the underlying intent of the proposed rule. Yet, for the reasons set forth more completely in the Generic Pharmaceutical Association (GPhA) comments to this docket, we believe that revised regulations cannot give full effect to the President's goal of putting a stop to the gaming of the system that "keep[s] generic off the market for frivolous reasons." Rather, a combined regulatory and legislative approach is the only effective means of restoring the proper

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balance between innovation and competition without unintentionally damaging other vital provisions of the Hatch-Waxman amendments.

For example, while we fully agree with FDA and FTC that Congress never envisioned *multiple* 30-month stays to be used to block generic competition, we share GPhA's concern that the proposed rule's limitation on the 30-month stay could undermine the Hatch-Waxman goal of ensuring timely resolution of patent disputes. The 30-month stay provides a powerful incentive for patent holders to bring an immediate action for infringement based on the notice letter. Eliminating the possibility of additional 30-month stays could encourage patent holders to wait to bring their infiringment actions after the generic product has been approved and, thus, potentially delay generic competition even longer.

As an interim solution to this problem, Barr proposes that ANDA applicants be given a choice as to whether to file a second notice letter when an additional patent has been listed. The applicant could elect to file the second notice letter, recognizing that the potential for an additional thirty month stay could encourage the patent holder to assert immediately that the patent was infringed by the filing of an ANDA. Or, the ANDA applicant could elect not to file the second notice letter, recognizing the risk that the patent holder might wait until the last possible moment to attempt to enforce its patent. As long as the choice belongs to the ANDA applicant, no harm should come from allowing the ANDA applicant to elect whether or not to file a second notice letter.

Barr is extremely appreciative of the President's unprecedented efforts to restore the originally intended Hatch-Waxman balance. The President's recent remarks concerning the proposed rule reflect a clear understanding of the issues and an unequivocal commitment to fix the problems. However, the President and FDA are limited in what they can do by our system of government. Many of the loopholes in the current statute can only be closed by Congress. Therefore, the type of effective reform that will produce real-world benefits to consumers necessarily requires a combined regulatory and legislative approach.

Sincerely,

Frederick J. Killion
Senior Vice President and General Counsel